

VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE

SHARON G. WINGATE,
EXECUTOR OF THE ESTATE OF
DOUGLAS GRAY WINGATE,
DECEASED,

Plaintiff,

v.

INSIGHT HEALTH CORP.,

JOHN M. MATHIS, M.D.,

ROBERT F. O'BRIEN, M.D.,

AND

IMAGE GUIDED PAIN MANAGEMENT,
P.C.,

Defendants.

Case No: CL12002547

AMENDED COMPLAINT

COMES NOW Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, by counsel, and files this Amended Complaint against the Defendants and states as follows:

PARTIES

The Plaintiff:

1. On September 18, 2012, Douglas Gray Wingate ("Mr. Wingate") died as a result of brain damage and other complications caused by fungal meningitis as a result of the epidural steroid injection which is at issue in this case.

2. On October 5, 2012 in the Commonwealth of Virginia Mr. Wingate's wife, Sharon G. Wingate ("Mrs. Wingate") duly qualified as the Executor of Mr. Wingate's Estate.

3. Mr. Wingate was a citizen of the Commonwealth of Virginia.

4. Mrs. Wingate is a citizen of the Commonwealth of Virginia.

Defendant Insight Health Corp.:

5. Insight Imaging-Roanoke is located at 2923 Franklin Road, S.W. Roanoke, Virginia 24014.

6. Insight Imaging is a trademarked name owned by Insight Health Corp. ("Insight Health"). Insight Imaging-Roanoke is a name licensed for limited purposes to Image Guided Pain Management, P.C. ("Image Guided"), and registered as a fictitious name. Image Guided is a professional corporation consisting of two shareholders and only two employees, John Mathis, M.D., and Robert O'Brien, M.D. (both radiologists).

7. Insight Health transacts business at 2923 Franklin Road, S.W., Roanoke, VA, under the fictitious name of Insight Imaging-Roanoke.

8. Insight Health has not registered the fictitious name of Insight Imaging-Roanoke in violation of Virginia Code §§ 59.1-69 and 59.1-70.

9. At all times and places pertinent to this action, Insight Health transacted business in the Commonwealth of Virginia under the fictitious name of Insight Imaging-Roanoke.

10. Unless otherwise specified in this Complaint, references to Insight Imaging-Roanoke or the "clinic" refer to the clinic at 2923 Franklin Road, S.W., Roanoke, VA, 24014 during the time periods subsequent to the purchase of the business by Insight Health in 2010.

11. At all times and places pertinent to this action, Insight Health owned, operated, controlled, and held the certificates of public need for, the Insight Imaging-Roanoke clinic and all related imaging equipment.

12. When it purchased the Insight Imaging-Roanoke business in 2010, Insight Health elected to contract with Image Guided and to have Dr. Mathis and Dr. O'Brien provide medical services at the Insight-Roanoke clinic.

13. In accordance with that decision, Insight Health maintained a contractual relationship with Image Guided that governed the relationship between the parties (the "Management Agreement"). The terms of the Management Agreement are subject to a Protective Order, so the next series of paragraphs are filed under seal.

14. (Relates to Management Agreement -- Filed Separately Under Seal)

15. (Relates to Management Agreement -- Filed Separately Under Seal)

16. (Relates to Management Agreement -- Filed Separately Under Seal)

17. (Relates to Management Agreement -- Filed Separately Under Seal)

18. Under the applicable Medicare rules, IDTF's (such as Insight Health) are imaging facilities that are not owned by either a hospital or a medical practice. In order to submit a singular Medicare invoice for medical and imaging aspects of the interventional procedures, Insight Health constructed the paperwork relationship as if Image Guided was actually the "clinic." But, in reality, it was not.

19. Before Insight Health purchased the Insight Imaging-Roanoke clinic, it was owned by Carilion (a hospital), so this type of legal manipulation was not necessary under the prior ownership.

20. Insight Health controlled the means and methods by which supplies and equipment were handled in connection with the services provided at the Insight Imaging-Roanoke clinic. Insight Health controlled the means and methods by which technicians and support staff were hired, trained, and performed their jobs in connection with such services. Insight Health controlled the means and methods of Image Guided with respect to aspects of the services and products provided at the Insight Imaging-Roanoke clinic relevant to this case.

21. At all times and places pertinent to this action, Insight Health made the actual decisions and arrangements relating to the sourcing, selection, procurement, storage, preparation of drugs, as well as the payment for, advertising of, record keeping and coding for, and billing for such drugs administered at Insight Imaging-Roanoke, including the epidural steroid drug that is at issue in this case.

22. Insight Health's control over the means and methods of Dr. Mathis and Dr. O'Brien in providing medical services included the power to prohibit the use of compounded drugs in October 2012 and to suspend the performance of epidural steroid injection procedures at the Insight Imaging-Roanoke clinic in October 2012.

23. In operating the Insight Imaging-Roanoke clinic, Insight Health set up a system that encouraged and created substandard medical care. It set up a paper work fiction that on one hand encouraged Image Guided to disregard important medical decisions about the purchase and handling of medications (such decisions being instead delegated to Insight Health with indemnity agreement back to Image Guided).

24. On the other hand, Insight Health set up important functions that to be handled in the name of Image Guided. To this it added a misleading designation of Image Guided as the named entity behind the fictitious name, Insight Imaging-Roanoke. These actions may have

successfully navigated the Medicare regulations to allow Insight Health (an IDTF) to pass as a medical practice-owned clinic. But, they also embedded mechanisms within the structure to shift blame to the doctors in the event of any significant problem, while leaving Image Guided with the understanding that Insight Health was in control.

25. Having set up this system, Insight Health then failed to designate a medical director, locally or nationally, to monitor and take responsibility for the decisions and actions that it was performing and undertaking. This left Insight Health's clinic manager, Paul Hellkamp, in charge of such functions --- and he was not competent to perform such responsibilities.

26. Insight Health's convoluted and misleading structure of these relationships at the Insight Imaging-Roanoke clinic, designed to bypass Medicare billing requirements, provided the perfect environment for shared negligence in which no one did anything appropriately because it was theoretically someone else's job. The system was all about money and not about patient care.

27. Insight Health is incorporated in the State of Delaware.

28. Insight Health's principal place of business is in the State of California.

29. At all times and places pertinent to this action, Insight Health advertised to the public that it was a national provider of diagnostic imaging services.

30. At all times and places pertinent to this action, Insight Health advertised to the public that it was committed to providing the best imaging experience possible, and it called this "Patients First care".

31. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was to "do the right thing".

32. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was integrity.

33. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was ethics.

34. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values of doing the right thing, integrity, and ethics took priority over profits.

35. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values of doing the right thing, integrity, and ethics took priority over expediency.

36. At all times and places pertinent to this action, Insight Health advertised to the public that it offered the highest quality of care through a network of outpatient imaging centers and mobile facilities.

37. At all times and places pertinent to this action, Insight Health advertised to the public that one of its centers was Insight Imaging-Roanoke, located at 2923 Franklin Road, S.W. Roanoke, Virginia 24014.

38. At all times and places pertinent to this action, Insight Health advertised to the public that one of the modalities that it provided at Insight Imaging-Roanoke was pain management image-guided therapeutics. It further advertised that the steroid medications that it used in such procedures were the trademarked, name brand, FDA-approved drugs, Depo-Medrol and Celestone Soluspan.

39. Insight Health procured, received, managed, stored, prepared, and provided to Mr. Wingate the epidural steroid that was injected into him on September 6, 2012 at the Insight

Imaging-Roanoke clinic, at issue in this case. The actual responsibility and mechanics for ordering, handling, receiving, managing, storing, preserving, and preparing steroid drugs for injection was accomplished solely by employees of Insight Health, who had its employee sign the Prescription Order Form used to obtain Mr. Wingate's steroid. Insight Health's clinic manager, Paul Hellkamp, authorized the purchase of the steroid drugs provided to Mr. Wingate. Insight Health is and was jointly or singularly responsible for the procurement of drugs such as Mr. Wingate's epidural steroid drug which is at issue in this case.

40. At all times and places pertinent to this action, Insight Health also did business through other employees and agents located in Roanoke and other places in the United States including, but not limited to, Paul Hellkamp, secretaries, nurses, technicians, staff, personnel, and physicians at Image Guided.

41. At the times and places pertinent to this action, Insight Health was liable for the actions and omissions of its other employees and agents located in Roanoke and other places in the United States including, but not limited to, Paul Hellkamp, secretaries, nurses, technicians, staff, and personnel, as well as Dr. Mathis and Dr. O'Brien.

42. Insight Health corresponded with Mr. Wingate with regard to the services, treatment and products he received on September 6, 2012 at the Insight Imaging-Roanoke clinic. In that correspondence, Insight Health addressed him as "Dear Valued Patient," and stated that "Insight Health Corp. is committed to providing our patients with superior diagnostic imaging services and to bill appropriately for the services we provide...../s/ Billing Department, Insight Health Corp." This correspondence provided a check to Mr. Wingate, drawn on an Insight Health account. A true and correct copy of the letter and check are attached as **Exhibit G**.

Defendants John M. Mathis, Robert O'Brien, and Image Guided:

43. Dr. John M. Mathis ("Dr. Mathis") is a citizen of the Commonwealth of Virginia.

44. Although Dr. Mathis had previously served as the Medical Director for an imaging center clinic at the same location when it was owned by the Center for Advanced Imaging, Dr. Mathis asserts that he did not serve or act as the Medical Director of Insight Imaging-Roanoke.

45. At certain times and places pertinent to this action, Insight Health held Dr. Mathis out to the public as its Medical Director for the Insight Imaging – Roanoke clinic.

46. Dr. Mathis asserts that, to the extent that Insight Health designated him as Medical Director for Insight Imaging-Roanoke, it did so without his permission or consent, that Insight Health never asked him to be a Medical Director, and that he was never compensated as a Medical Director for Insight Imaging-Roanoke.

47. If Dr. Mathis did not agree to be or act as the Medical Director of Insight Imaging-Roanoke during the times and places pertinent to this action, then Insight Health falsely designated and held out Dr. Mathis to the public as its Medical Director, and Insight Health delegated to non-medical staff the important patient care function of choosing safe and effective drugs for its patients.

48. If Dr. Mathis agreed to be or acted as the Medical Director of Insight Imaging-Roanoke during the times and places pertinent to this action, then he was jointly responsible for the choices regarding the procurement and handling of drugs at the clinic, such as Mr. Wingate's epidural steroid drug that is at issue in this case.

49. Dr. Mathis' Drug Enforcement Agency (DEA) number and his name were used by Insight Health to procure the steroids that were injected into Mr. Wingate at the Insight Imaging-Roanoke clinic. This was consistent with the business agreement between Image

Guided and Insight Health. However, by allowing his DEA number and name to be used in this regard, he and Image Guided are and were jointly or singularly responsible for the procurement of drugs, such as Mr. Wingate's epidural steroid drug that is at issue in this case.

50. At all times and places pertinent to this action, Dr. Mathis was an employee and/or agent of Insight Health and Image Guided acting in the course and scope of his employment or agency.

51. At all times and places pertinent to this action, Insight Health and Image Guided acted through their employees and agents including, but not limited to, Dr. Mathis.

52. At all times and places pertinent to this action, Insight Health and Image Guided were liable for Dr. Mathis' actions and omissions.

53. Dr. Robert F. O'Brien ("Dr. O'Brien") is a citizen of the Commonwealth of Virginia.

54. Dr. O'Brien performed Mr. Wingate's epidural steroid injection at Insight Imaging-Roanoke.

55. Regardless whether there was or was not a Medical Director, who was or was not the Medical Director, or who did or did not participate in the procurement of drugs for Mr. Wingate, as the physician performing the injection into Mr. Wingate's spine, Dr. O'Brien owed independent and joint duties to Mr. Wingate with regard to the medications selected and injected.

56. At all times and places pertinent to this action, Dr. O'Brien was an employee and/or agent of Insight Health and Image Guided acting in the course and scope of his employment or agency.

57. At all times and places pertinent to this action, Insight Health and Image Guided acted through their employees and agents including, but not limited to, Dr. O'Brien.

58. At the times and places pertinent to this action, Insight Health and Image Guided were liable for Dr. O'Brien's actions and omissions.

59. Image Guided is incorporated in the Commonwealth of Virginia.

60. Image Guided's principal place of business is in the City of Roanoke, Virginia.

JURISDICTION AND VENUE

61. Subject matter jurisdiction is proper pursuant to Virginia Code § 17.1-513.

62. Personal jurisdiction over Insight Health is proper pursuant to at least Virginia Code §§ 8.01-328.1(A)(1), (2), (3), (4) & (6).

63. Personal jurisdiction over Image Guided, Dr. Mathis, and Dr. O'Brien is proper pursuant to at least Virginia Code §§ 8.01-328.1(A)(1), (2), (3) & (6).

64. Venue is proper pursuant to Virginia Code §§ 8.01-262(1) & (2).

FACTS

65. At all times and places pertinent to this action, Mr. Wingate was a patient of Insight Health, seeking and obtaining services and/or treatment from Insight Health. Insight Health owed professional duties to Mr. Wingate, including the duty of reasonable care. Among other things, these duties included the following:

- a. Insight Health represented to Mr. Wingate a commitment to provide him with superior services and to appropriately bill for the services that it provided. It owed these duties to Mr. Wingate.
- b. Insight Health specifically represented in its advertisements a commitment to take nothing for granted and to carefully scrutinize all products and services offered to patients such as Mr. Wingate. It owed these duties to Mr. Wingate.
- c. Insight Health specifically represented in its advertisements a commitment to provide the best imaging experience possible; to act ethically; to act with integrity; to do the right thing; to place patient care first; and, to place ethics,

integrity, doing the right thing, and patient care above profits. It owed these duties to Mr. Wingate.

- d. Insight Health owed Mr. Wingate a duty to use reasonable skill, due diligence, and reasonable care in selecting, procuring, managing, investigating, maintaining, preparing, and inspecting drugs that were provided to him.
- e. Insight Health owed a duty to know and appreciate the source from which it obtained steroids provided to patients at the Insight Imaging-Roanoke clinic.
- f. Specifically, with regard to the sourcing and procurement of compounded methylprednisolone acetate, Insight Health had a duty to understand and appreciate compounding pharmacies and the distinctions between such pharmacies and FDA-regulated drug manufacturers as well as the risks associated with compounding pharmacies and “sterile” injectables procured from such sources.
- g. By procuring a compounded parenteral steroid suspension for injection into persons such as Mr. Wingate, Insight Health owed a duty to conduct careful investigation and screening of the source compounding pharmacy, its methods and procedures, sterility practices, quality assurance practices, accreditation status, and legal compliance of such compounding pharmacy before purchasing parenteral medications such as the steroids injected into him.
- h. By procuring a compounded parenteral steroid suspension for injection into persons such as Mr. Wingate, Insight Health owed a duty to confirm and investigate the expiration or “beyond use” dating for such products to make sure that such dates were reasonable and in compliance with USP-NF requirements and standards.
- i. By procuring a compounded parenteral steroid suspension for injection into persons such as Mr. Wingate, Insight Health owed a duty to understand the methodology used by such compounding pharmacy in connection with the production of such drugs.
- j. By procuring a compounded parenteral steroid suspension for injection into persons such as Mr. Wingate, Insight Health owed a duty to visually inspect such compounding pharmacy where such drugs were to be produced.

- k. By procuring a compounded parenteral steroid suspension for injection into persons such as Mr. Wingate, Insight Health owed a duty to adequately inform Mr. Wingate of the source of medications which it procured and presented for injection into his body; and to obtain his informed consent for the delivery of such drugs.
- l. Insight Health owed a duty to Mr. Wingate to inform him that FDA-approved and regulated alternative steroid medications were available instead of the compounded drug.
- m. Insight Health owed a duty to adequately inform Mr. Wingate of the source of medications which it procured and presented for injection into his body; and to obtain his informed consent for the delivery of such drugs.
- n. Insight Health owed Mr. Wingate a duty to take reasonable steps with skill and diligence to ensure that the drugs that it procured and managed for delivery to him at Insight Imaging-Roanoke were safe and effective.
- o. Insight Health owed Mr. Wingate a duty to purchase and use of FDA-approved drugs unless his special needs required compounding of drugs that were not commercially available, in which instance Insight Health owed Mr. Wingate a duty to inform him of this and the reasons why his needs required a compounded drug.
- p. If compounded drugs were to be procured and used for Mr. Wingate, Insight Health owed Mr. Wingate a duty to carefully handle, store, manage, and preserve medications such as the steroid the was provided to him at the Insight Imaging-Roanoke clinic on September 6, 2012.
- q. Insight Health owed Mr. Wingate a duty to carefully and timely inspect all medications provided to him, including the steroid that Insight Health provided for him on September 6, 2012.
- r. Insight Health owed Mr. Wingate a duty to be aware of dangers associated with compounded parenteral products such as the steroid that was provided to him on September 6, 2012.

- s. Insight Health owed Mr. Wingate a duty to operate the Insight Imaging-Roanoke clinic in such a way as to be aware of and avoid dangers posed by medication practices at such clinic. This duty included:
 - i. the duty to be informed and stay informed as to developments, dangers and circumstances relevant to procurement of medications;
 - ii. the duty to adequately inform Image Guided and its physicians of adverse health events that signaled possible problems with medications (so that it and its physicians could make reasonable patient care decisions);
 - iii. the duty to insure that proper paper work was received with medications;
 - iv. the duty to use proper prescription processes for procuring compounded medications for Mr. Wingate and other patients; and
 - v. the duty to make sure that "informed consent" forms prepared by Insight Health accurately and completely disclosed the risks associated with the procedures and medications provided.
- t. Insight Health owed a duty to Mr. Wingate to keep accurate records of his medical treatment, to accurately bill him for services provided, and to provide him with accurate information as to the treatment and services provided to him at the Insight Imaging-Roanoke clinic.

66. At all times and places pertinent to this action, Image Guided, Dr. O'Brien, and their agents had a healthcare provider-patient relationship with Mr. Wingate.

67. Image Guided, its agents, and Dr. O'Brien owed Mr. Wingate a duty to provide medical services consistent with the standard of care, skill and diligence that a reasonably prudent healthcare provider would use in all aspects of the patient-healthcare-provider relationship, including, but not limited to, the sourcing, selecting, procuring, prescribing, managing, investigating, maintaining, preparing, inspecting, drawing, and injecting of drugs that were provided to him. These include all of the forgoing duties listed in paragraph 65 with regard to Insight Health. Even to the extent that Image Guided and/or Dr. O'Brien delegated any such

responsibilities to Insight Health, they remained at least jointly responsible for such tasks, owed the same duties, and cannot avoid joint liability for such actions by delegating such duties to Insight Health.

68. Image Guided and its agents at all times owed Mr. Wingate duties that included, without limitation, the following:

- a. to know and understand the dangers associated with compounded drugs and the relative distinctions between compounded drugs and drugs from FDA-regulated manufacturers;
- b. to know and understand the nature and source of the medications provided to Mr. Wingate;
- c. to ensure that only FDA-approved drugs were used in his treatment;
- d. to only allow or recommend the use of compounded parenteral medications if his individual medical condition required treatment with a drug that was not commercially available from an FDA-regulated drug manufacturer;
- e. to explain such necessity to Mr. Wingate before proceeding with any injection of compounded drugs;
- f. to obtain Mr. Wingate's informed consent before so proceeding;
- g. to carefully screen and inspect any compounding pharmacy before using compounded parenteral drugs from such pharmacy;
- h. when compounded drugs were selected (appropriately or inappropriately), to maintain vigilance with regard to such compounded drugs and potential problems with the compounder;
- i. to properly understand and investigate adverse health events occurring with drugs of procedures at the Insight Imaging-Roanoke facility so as to make reasonable health care decisions for patients such as Mr. Wingate who would receive such drugs; and
- j. to keep accurate records of his medical treatment and to provide him with accurate information as to the treatment and services provided to him.

69. At all times and places pertinent to this action, Mr. Wingate relied upon the services and treatment provided by Insight Health and its employees and agents, who had specialized training and superior knowledge regarding the sourcing, selecting, procuring, managing, investigating, maintaining, preparing, inspecting, drawing, and injecting of drugs that were provided to him.

70. At all times and places pertinent to this action, Mr. Wingate relied upon the advice and treatment provided by Image Guided, Dr. O'Brien, and their agents, who had specialized training and superior knowledge as to all aspects of the treatment provided to Mr. Wingate at the Insight Imaging-Roanoke clinic.

71. Insight Health and its employees and agents intended to and in fact did source, select, procure, manage, prepare, and draw compounded methylprednisolone acetate for the epidural steroid injection provided to Mr. Wingate which is at issue in this case.

72. Image Guided and Dr. O'Brien injected the steroid into Mr. Wingate.

73. The use of methylprednisolone acetate in epidural steroid injections has never been approved by the Food and Drug Administration ("FDA").

74. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, that the use of methylprednisolone acetate in epidural steroid injections has never been approved by the FDA.

75. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, that use of methylprednisolone acetate in epidural steroid injections is an off-label use.

76. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, the importance of purchasing safe and effective drugs

for patients at Insight Imaging-Roanoke and this importance was heightened by the fact that the use of methylprednisolone acetate in epidural steroid injections has never been approved by the FDA.

77. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, the danger to which Mr. Wingate and other patients at Insight Imaging-Roanoke would be exposed if unsafe and/or ineffective drugs were purchased or used for patients.

78. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, that quality assurance, sterility and potency are very high priorities for any medication, but the stakes are enormously high for a sterile, preservative-free, steroid suspension, parenteral products administered epidurally.

79. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, that only FDA-approved drugs from an FDA-regulated manufacturer should be procured and used for such epidural steroid injections and that compounded steroid suspensions should never be procured or used unless the special needs of a specific patient require compounding of drugs that are not commercially available. They knew or should have known that Mr. Wingate had no such special needs.

80. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, that steroids suppress the human immune system, can act to exacerbate fungal growth, are injected in very close proximity to the central nervous system, and can transmit pathogens that can cause disease and death if not properly and carefully prepared.

81. Rather than obtaining medication from an FDA-regulated drug company, Insight Health sourced and procured steroids for injection into Mr. Wingate from New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), a compounding pharmacy located in Framingham, Massachusetts.

82. Compounding pharmacies, like NECC, have emerged over the past decade or so as a lightly (if at all) regulated shadow market for drugs like the steroids used in epidural injection procedures. These compounding pharmacies typically offer lower prices and, in some instances, they tout that their versions of the steroids are preservative free, unlike some of the FDA-approved versions of the drugs. Traditionally, however, compounding pharmacies have operated within hospitals or on a very small scale, mixing (or "compounding") special drug products to meet the individualized needs for specific patients, pursuant to a valid patient-specific prescription.

83. Because they are designed and expected to compound small quantities of drug products in forms that are not commercially available and are used promptly, compounding pharmacies are not regulated by the FDA. However, compounders have sought to move beyond this limited role in pursuit of profits by producing larger and larger quantities of commercially available drugs in competition with FDA-regulated drug manufacturers.

84. The regulatory laws have largely not caught up with this new compounding pharmacy business model change. Accordingly, in 2012, compounding pharmacies were generally regulated under state law applicable to pharmacies and pharmacists.

85. NECC operated in Massachusetts and was subject to Massachusetts laws. Clinics purchasing from NECC were also required to comply with Massachusetts laws, even when the drugs were sold into other states. When selling into Virginia, NECC and any Virginia clinic

purchasing from NECC, were also required to comply with Virginia law in order to fill prescriptions in Virginia.

86. The NECC steroid that Insight Health procured for injection into Mr. Wingate was methylprednisolone acetate. NECC advertised such drug as a knock-off of the brand name drug, Depo-Medrol, which is manufactured by the FDA-regulated company, Pharmacia & Upjohn Company, a Division of Pfizer, Inc. ("Pfizer"). However, there is very little similarity between the NECC steroid and Pfizer's Depo-Medrol.

87. Numerous alternative and safer sources existed for Insight Health to procure appropriate steroid solutions or suspensions for injection into Mr. Wingate. Other FDA-regulated drug manufacturers produce alternative steroid products suitable for epidural injection, with and without preservatives.

88. Other FDA-regulated drug manufacturers also produce sterile generic versions of the innovator product, Depo-Medrol, pursuant to exact FDA-approved requirements and regulations. These drugs are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (a/k/a the "Orange Book"). In order to be considered a generic drug, the drug must be a "therapeutically equivalent drug product," as defined in the Orange Book. Generic drugs are literally "equivalent" to the innovator (name brand) drug. Compounded drugs such as NECC's methylprednisolone acetate are not generic drugs.

89. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, that Depo-Medrol and generic therapeutically equivalent products for Pfizer's Depo-Medrol, may be purchased from FDA-regulated drug manufacturers in the United States, with or without benzyl alcohol (a preservative found in multi-use vials of Depo-Medrol).

90. Insight Health, Image Guided, and Dr. O'Brien, together with their employees and agents knew, or should have known, that FDA-regulated drug manufacturers, such as Pfizer, operate under strict FDA guidelines and regulations. These include regulations known as good manufacturing practice regulations (GMP's).

- a. They knew or should have known that compounding pharmacies such as NECC operate under rules and standards that are magnitudes less in terms of quality assurance.
- b. They knew or should have known that FDA-regulated manufacturers are required to report adverse health events, while pharmacy compounders are not.
- c. They knew or should have known that the FDA has warned against the purchase of sterile products from compounding pharmacies.
- d. They knew or should have known that medical literature has publicized the dangers associated with purchasing parenteral medications from compounding pharmacies and warned against such use.
- e. They knew or should have known that compounding pharmacies are not required to establish "expiration" dating from drugs in the manner that FDA-regulated drugs do.
- f. They knew or should have known that serious adverse health events have occurred and been reported in journals and in the media arising from the use of compounded drugs.

91. Rather than purchasing and using FDA-regulated steroids from drug manufacturers, Insight Health chose to purchase knock-off methylprednisolone acetate from NECC.

92. This decision and practice was contrary to Insight Health's nominal corporate policy and practice of purchasing medicines and supplies from a centralized national distributor of FDA-regulated drugs, McKesson Corporation.

93. In order to procure the knock off steroids from NECC, Insight Health prepared "Prescription Order Forms" that it sent to NECC. Rather than providing a patient-specific prescription in order to obtain compounded drugs for that specific patient, Insight Health completed the Prescription Order Form by attaching lists of approximately 40 names and protected health information of prior patients who had already received treatment at the Insight Imaging-Roanoke clinic. This former patient protected health information included the patient's name, referring physician name, gender, medical treatment received, date of procedure, time of procedure, file number, home phone number, date of birth, and reason for exam.

94. In exchange for these 40 names, Insight Health would then receive 200 vials of NECC steroids with each order (a 5:1 ratio). The individual vials then arrived in foil pouches, five vials to a pouch, with the exterior of the pouch indicating that the contents fulfilled the prescription of one named former patient.

95. By contrast, when purchasing from an FDA-regulated drug manufacturer or distributor, clinics such as Insight Imaging-Roanoke are not required to provide patient specific prescriptions or any prescriptions at all. Rather, they are allowed to stock such drugs for clinical use.

96. In the Summer of 2012, before Mr. Wingate's injection, an inspection of the Roanoke Insight-Imaging clinic was conducted by Insight Health's corporate safety officer, Linda Massaro. Ms. Massaro observed the unorthodox prescription process by which Insight

Health obtained prescription drugs with one (former) patient's name on the packaging, and then injected the drug into a completely different (new) patient.

97. Insight Health's employee, Ms. Massaro, objected to this process and informed the staff that the name on the prescription and/or its packaging should match the name of the patient receiving that drug. She instructed the staff to change it. When told that this process was simply the way things worked when you ordered drugs from NECC, Insight Health's safety officer did nothing further.

98. Insight Health's policies, procedures and guidelines require compliance with patient privacy expectations, rules and regulations. In fact, all of the Insight Health employees at the Insight Imaging-Roanoke clinic are evaluated periodically as to their respective compliance with these important issues. Although the NECC Prescription Order Form process violated these expectations, rules and regulations in every respect, Insight Health did nothing.

99. There was no legitimate reason for Insight Health to use the NECC knock-off steroid for Mr. Wingate. Insight Health had a stock of name brand, FDA-regulated Depo-Medrol at the Insight Imaging-Roanoke clinic on the day that Mr. Wingate received his epidural steroid injection at the clinic. Rather than provide him with this FDA-regulated medication, Insight Health prepared the syringe for his injection with NECC's compounded knock-off drug. Depo-Medrol, generic versions of Depo-Medrol, and a host of other FDA-regulated steroid suspensions and solutions were commercially available for purchase and use in Mr. Wingate's injection at the time of his injection.

100. Purchase of parenteral medications from any compounding pharmacy should only be done in situations of specific and defined need for a specific patient's medical condition. If

such conditions exist, the purchaser and practitioner must exercise great care and diligence in investigating the compounding pharmacy.

101. Insight Health, Image Guided, and Dr. O'Brien conducted absolutely no investigation or inquiry whatsoever regarding NECC.

102. Insight Health knew, however, that NECC was engaged in the very risky process of producing and marketing vast batches of this complicated "high risk" steroid suspension compound without preservatives, thousands at a time. For example, the NECC lot number provided to Mr. Wingate was NECC lot # 06292012@26. Insight Health purchased two separate 200 count batches of this NECC lot # 06292012@26, ordered on July 25, 2012 (with delivery on July 26) and again on August 16, 2012 (with delivery on August 17). Both of these orders (separated by three weeks) were fulfilled overnight by the same batch number of methylprednisolone acetate from NECC. At this rate, Insight Health was purchasing about 200 vials of the NECC steroid every 3 weeks. Insight Health knew or should have known that NECC was stocking large quantities of these preservative free steroids from single lots.

103. The slightest bit of inquiry or investigation by Insight Health would have confirmed that NECC was a dangerous mess. It is housed in sprawling complex of old buildings, located adjacent to railroad tracks, surrounded by a garbage facility, with a sweat-shop phone bank of 100 plus cubicle-enclosed telemarketers working the phones to sell more compounded drugs. The surrounding garbage facility handles all manner of waste products including used mattresses, recycled on-site from sources such as hospitals, prisons, hotels, and dormitories. A photograph of NECC's facility is attached as **Exhibit A**.

104. When investigators from the FDA and Massachusetts went to the NECC facility on September 26, 2012, just days after Mr. Wingate died, they found many violations of sanitary

standards. Plainly, NECC did not comply with USP-NF standards in compounding drugs. The same would have been apparent to Insight Health had it bothered to conduct any investigation. But, it did none and claims to have known nothing of these basic facts.

105. Typically, when Insight Health received batches of new knock-off steroids from NECC, the drugs came with a microbiology report and a certificate of analysis that were supposed to offer some assurance that the samples of the lot number had been tested by an independent laboratory and found to be sterile. However, for the lot number provided to Mr. Wingate, # 06292012@26, no such microbiology reports were received by Insight Health with the delivery.

106. Prior to Mr. Wingate's injection, one of Insight Health's employees noticed the missing microbiology reports and certificates of analysis that were supposed to be filed in a special folder within the clinic. She reported this to another Insight Health employee, but neither did anything else about it. Insight health did not inform Image Guided, Dr. Mathis, and Dr. O'Brien of this lapse. Insight Health continued to present the steroids for injection into patients like Mr. Wingate, filling syringe after syringe with contaminated steroids.

107. It is apparent that Insight Health never carefully examined or understood the microbiology reports and certificates of analysis in the first instance. USP-NF guidelines and rules require that a minimum sampling of the finished product (in its terminal containers) should be tested for sterility. Here, the reports that Insight Health actually received reflect, instead, that NECC simply sent off special different sized test vials containing a vastly insignificant amount of finished product for testing.

108. NECC made its knock off steroids through a process of taking non-sterile ingredients and placing them into an aqueous mixture that then had to be rendered sterile. Even

without the large batches, NECC's process made the methylprednisolone acetate a high risk compound.

109. Insight Health, Image Guided, Dr. O'Brien, and their employees and agents knew, or should have known, that NECC's process made the methylprednisolone acetate a high risk compound.

110. NECC acted as a wholesale distributor by selling large quantities of methylprednisolone acetate. But, it was not licensed or registered to do so.

111. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC acted as a wholesale distributor by selling large quantities of methylprednisolone acetate. But, it was not licensed to do so.

112. Under Virginia law, compounding pharmacists must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary). Virginia Code §54.1-3410.2(E).

113. NECC failed to comply with USP-NF standards.

114. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not compliant with USP-NF standards.

115. Moreover, pharmacists and pharmacies may not engage in "the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products." Virginia Code §54.1-3410.2(H)(2).

116. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was producing enormous batches of commercially available methylprednisolone acetate, which NECC then sold in bulk.

117. Within less than three months during the general time frame pertinent to this action, Insight Health alone purchased 1000 doses of methylprednisolone acetate from NECC.

118. NECC was registered in the Commonwealth of Virginia as a non-resident pharmacy, but it is not and was not registered as a wholesale distributor of prescription drugs as required by Virginia Code §54.1-3435.01(A).

119. Insight Health and its employees and agents knew, or should have known, that NECC was not registered to distribute prescription drugs wholesale in the Commonwealth of Virginia, but they purchased from NECC as if it was.

120. NECC is not accredited by the Pharmacy Compounding Accreditation Board ("PCAB") or any other similar organizations, such as The Joint Commission, that offer some level of independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

121. Insight Health, Image Guided, Dr. O'Brien, and their employees and agents knew, or should have known, that NECC was not an accredited compounding pharmacy. Thus, Insight Health, Image Guided, and Dr. O'Brien blindly purchased from this extremely shady compounding pharmacy without even the minimal assurance that accreditation would have provided. They simply did not care to investigate or inquire, so they did not.

122. Although incredible, Insight Health's clinic manager, Paul Hellkamp, asserts that, at the time of Mr. Wingate's injection, he did not even know that NECC was a compounding pharmacy. Likewise, he asserts that he did not know what a compounding pharmacy was by comparison to an FDA-regulated drug manufacturer such as Pfizer.

123. Image Guided's Dr. Mathis and Dr. O'Brien assert a similar lack of understanding of the basic differences between compounding pharmacies and FDA-regulated drug

manufacturers, claiming as well that they did not even realize that the steroids were actually being purchased from NECC. In fact, Image Guided, Dr. Mathis and Dr. O'Brien assert that they never saw the vials of medication because they did not draw their own medications from the vials. Rather, they simply walked into the procedure room, placed the needle with x-ray (fluoroscope) guidance, and injected whatever Insight Health put into the syringe.

124. Insight Health, Image Guided, and Dr. O'Brien did, however, know that the steroid being injected into Mr. Wingate and other patients contained no preservatives. They also knew or should have known that the NECC drugs asserted a "beyond use date" of approximately six months from the date of manufacture (such information being readily available on the label). They also knew or should have known that Insight Health provided no refrigeration or other preservation procedures for such medication. Rather, it was simply stored at room temperature.

125. The steroid injected into Mr. Wingate should not have been stored at room temperature for months before injection into Mr. Wingate. It was made on June 29, 2012, and was stored unrefrigerated by Insight Health from the time it was received until it was injected into him on September 6, 2012 (69 days after production). USP Chapter 797 specifies a beyond use date for "high risk" compounds (like the NECC methylprednisolone preservative free suspension) of 24 hours at room temperature and 3 days with refrigeration.

126. It was unreasonable and a breach of the duty of reasonable care for Insight Health to simply accept the six month "beyond use" date specified by NECC on the vials of methylprednisolone acetate that it procured from NECC.

127. It was unreasonable and a breach of the duty of reasonable care for Insight Health not to refrigerate the preservative-free steroids procured from NECC.

128. Insight Health, Image Guided, and Dr. O'Brien and their employees and agents knew, or should have known, that preservative free methylprednisolone acetate heightens the danger of the drug if it is not produced to the highest standards, maintained in an environment to preserve sterility, and used promptly after production.

129. Insight Health's actions in receiving, storing and using Mr. Wingate's "high risk" steroid in violation of accepted "beyond use" standards, allowed fungal pathogens to grow and multiply in the vial of steroids, in breach of its duty to Mr. Wingate. Had Insight Health acted in accordance with and insisted on purchasing drugs in accordance with accepted and applicable "beyond use" standards, Mr. Wingate would not have been injected with a contaminated steroid. Even if he had been injected with a contaminated steroid used within the applicable "beyond use" standards, he would not have suffered grave injury or death.

130. Image Guided and Dr. O'Brien breached their duty of care to Mr. Wingate by failing to assure that the steroids used in his injection were purchased, stored and used in accordance with accepted and applicable "beyond use" standards. Had Image Guided and Dr. O'Brien not breached this important duty, Mr. Wingate would not have been injected with a contaminated steroid. Even if he had been injected with a contaminated steroid used within the applicable "beyond use" standards, he would not have suffered grave injury or death.

131. Mr. Wingate was not the first patient at Insight Imaging-Roanoke to receive the NECC steroid. Rather, it was routinely purchased by Insight Health and injected into patients for years preceding his injection on September 6, 2012.

132. In August of 2011, a substantial adverse health event occurred at Insight Imaging-Roanoke. A patient received a series of three consecutive epidural steroid injections at the clinic with the NECC steroid. After her third injection, she became very sick and was diagnosed with

bacterial meningitis arising from her epidural steroid injections. She was hospitalized for seven days and sent home with PIC line through which she was administered antibiotics for an additional two weeks (the “2011 Bacterial Meningitis Case”).

133. Regarding the 2011 Bacterial Meningitis Case, Insight Health was fully informed of this patient’s diagnosis, hospitalization, and subsequent treatment for bacterial meningitis, through an October 11, 2011 letter from the patient’s attorney. Yet, it did nothing. It did not appropriately investigate, follow up, or act on this information.

134. At the time of the event, Dr. O’Brien was aware of the initial complaint by the patient regarding the 2011 Bacterial Meningitis Case, but he dismissed it as a misdiagnosis even though he had no information on which to base such an incorrect assumption. He did not appropriately investigate, follow up, or act on this information.

135. Dr. Mathis asserts that he was never even told of the 2011 Bacterial Meningitis Case during the relevant time period.

136. The 2011 Bacterial Meningitis Case was a very significant adverse event at the Insight Imaging-Roanoke clinic. Bacterial meningitis is an extremely rare complication of epidural steroid injection. To place this event in context, Dr. O’Brien and Dr. Mathis had performed over 25,000 epidural steroid injections up to this time, and they had never had a serious complication such as bacterial meningitis.

137. Other well-publicized cases of bacterial meningitis had occurred with epidural steroid injection patients at other clinics when compounded steroids were used. Insight Health, Image Guided, and Dr. O’Brien should have known this and acted accordingly.

138. Bacterial meningitis arising from an epidural steroid injection is a plain indication of the introduction of bacterial pathogens from a limited number of possible sources: the needle,

the skin of the patient (which would have been cleaned and sterilized prior to the injection), or the drug(s) injected (which would indicate that the drugs were not sterile).

139. The standard of care and the duty of reasonable care required significant investigation of this incident and inquiry with the compounder of the drug (NECC). Here, absolutely none of that occurred, and the business of ordering drugs from NECC continued as usual until Insight Imaging-Roanoke patients, like Mr. Wingate, contracted fungal meningitis from the same NECC drug a year later.

140. It was a breach of the standard of care and the duty of reasonable care for Insight Health, Image Guided, and Dr. O'Brien not to investigate and then fully vet the possible sources of the infection --- including contaminated drugs from NECC. Until reasonable conclusions could be drawn from the investigation and inquiry that should have occurred, it was a breach of the standard of care and the duty of reasonable care to continue to inject or purchase additional steroids from NECC. The claims of bacterial meningitis should have been confirmed; and products should have been quarantined pending further investigation.

141. If Insight Health, Image Guided, or Dr. O'Brien had made any reasonable inquiry regarding NECC following the 2011 Bacterial Meningitis Case, they would have discontinued purchasing from NECC permanently.

142. To the extent that Insight Health did not inform Image Guided and/or its physician employees of the October 2011 letter regarding the 2011 Bacterial Meningitis Case and/or seek the guidance of Image Guided and the doctors relating thereto, then such inaction by Insight Health was a further breach of its duty of reasonable care and the applicable standard of care.

143. Numerous events and issues arose at the Insight Imaging-Roanoke clinic before Mr. Wingate's injection, all or any of which should have woken Insight Health, Image Guided, and Dr. O'Brien from their collective negligent disregard and ignorance regarding the source of steroids being procured and injected into patient's spines. Although careful investigation was required in any event before drugs from NECC could even be considered for injection into patients, any one of these "red flag" events, conditions or processes should have put an immediate end to the use of NECC's steroids and, at the very least, careful examination of NECC. Each one of these red flags was completely ignored. They include:

- a. The unorthodox and improper prescription order procedure by which Insight Health obtained the NECC drugs in the first place;
- b. The vast quantity of drugs produced by NECC;
- c. The 2001 Bacterial Meningitis Case;
- d. The 2012 inspection by Insight Health's corporate safety officer, Linda Massaro. Ms. Massaro where she observed and warned against the unorthodox process by which Insight Health obtained prescription drugs with one (former) patient's name on the packaging, and then injected the drug into a completely different (new) patient; and
- e. The missing microbiology reports and certificates of analysis were noticed by Insight Health before Mr. Wingate's injection, and then ignored, like all the preceding red flags.

144. Despite all of these red flags, business went on as usual at the Insight Imaging-Roanoke clinic. Insight Health continued to purchase and handle the NECC drugs, filling syringe after syringe for injection into un-knowing patients. Image Guided and Dr. O'Brien

continued to walk into the procedure room and shoot the unknown syringe contents into the spines of un-knowing patients such as Mr. Wingate.

145. A similar pattern of absolute carelessness was evident even after NECC issued an “urgent” recall of three lots of steroids (1000 doses of medication) that Insight Health had procured from NECC between June 15, 2012 and September 6, 2012. Insight Health received a telephone voice message from NECC in the early morning hours of September 26, 2012, warning of an emergency with regard to unspecified particulate matter in the NECC steroids and providing a number for Insight Health to call for more information. Later in the day, an NECC fax arrived at Insight Health confirming an urgent recall of the 1000 doses that had been sold to Insight Health over the preceding months. The recall noted that it was due to “foreign particulate matter,” and again offered to field any questions about the recall.

146. Insight Health, Image Guided and Dr. O’Brien simply continued performing scheduled epidural steroid injection. However, instead of using the NECC knock-off steroid, they used the real FDA-regulated, name brand drug, Depo-Medrol (which they had on the shelf at the clinic).

147. Other than this one change, after receiving this “urgent” and “emergency” information from NECC on September 26, 2012, Insight Health did absolutely nothing for the next five days. It did not call NECC, it did not call patients who had received the drugs, and the clinic manager did not even tell his corporate superiors about the recall until October 1. Like all of the other warnings and “red flags” before it related to patient safety and care, this written “urgent”, “emergency” red flag went untended. Insight Health did not appropriately investigate, follow up, or act on this information.

148. Sterilization techniques, quality control measures, highly sterile environments and sterility testing are crucial to properly producing methylprednisolone acetate without preservatives.

149. Insight Health, Image Guided, Dr. O'Brien, Dr. Mathis and their employees and agents knew, or should have known, that sterilization techniques, quality control measures, highly sterile environments, and sterility testing were crucial to the methylprednisolone acetate that they were going to inject in its patients' spinal canals.

150. Insight Health, Image Guided, Dr. O'Brien, Dr. Mathis and their employees and agents knew, or should have known, that NECC was an unaccredited compounding pharmacy producing a high-risk compound, starting with non-sterile components.

151. Insight Health, Image Guided, Dr. O'Brien, Dr. Mathis and their employees and agents knew, or should have known, that NECC's drugs and production processes were unsanitary, unsterile, and lacked adequate quality control measures, and that NECC operated in a facility surrounded by a garbage and waste center.

152. Insight Health, Image Guided, Dr. O'Brien, Dr. Mathis and their employees and agents knew, or should have known, that NECC was a profoundly dangerous source of methylprednisolone acetate. The only way that all or any of them were able to continue in the pattern of disregard of these dangers was through an entrenched and unreasonable negligence and indifference.

153. The dangers with the NECC compounded steroids were so real and so significant, that it was truly not a matter of "if" patients would ultimately be harmed by these drugs, but simply a matter of "when."

154. The fungal meningitis outbreak that occurred with patients at the Insight Imaging-Roanoke clinic in 2012 was:

- a. a completely predictable risk,
- b. associated with reckless purchases and injections of complicated, compounded, preservative free steroids for injection into spinal canals,
- c. from a wholly-unknown compounding source,
- d. into which none of the defendants had conducted any investigation or inquiry,
- e. and, about which, the defendants individually and collectively ignored all general and specific warnings.

155. The only possible justification for Insight Health purchasing steroids from NECC was that the drugs were cheaper than the FDA-approved steroid suspensions, like Depo-Medrol from Pfizer. Insight Health wanted to save money on the medical expenses for the epidural steroid injection; and, the NECC knock-off was cheaper. This price differential, however, was no excuse for purchasing methylprednisolone acetate from NECC, which was an unaccredited, sprawling compounding pharmacy that: (a) produced its drugs in the same complex as a waste facility; (b) produced the drugs in bulk batches (making mistakes more likely); (c) did not properly sterilize the drugs; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately representative samples of the drugs independently tested by an FDA-approved testing facility before releasing them for distribution; and (g) did not comply with USP-NF standards.

156. Image Guided, Dr. O'Brien and Dr. Mathis assert that they never would have used the methylprednisolone acetate from NECC if they had been properly informed of the facts relating to NECC. Because they were uninformed of the facts, they were unable to make reasonable decisions regarding patient care, including the care of Mr. Wingate. For their part,

they expected Insight Health to provide a safe and effective form of methylprednisolone acetate in single dose vials for injection into patients. Relying on Insight Health, they did nothing and purport to have known nothing.

157. Similarly, Insight Health asserts that it did nothing and knew nothing. It repeatedly purchased the NECC steroids for use at its clinic and in accordance with its contractual obligation to purchase and supply such medicines; but, it attempts to shift responsibility for such actions to the doctors.

158. Insight Health cannot avoid liability. It controls the means and methods employed at the Insight Imaging-Roanoke clinic. After the 2012 recall of the NECC steroids and the ensuing illness and death, Insight Health issued an edict that no compounded drugs would be used at any of its clinics, nationwide (including Roanoke). Image Guided and its doctors were given no choice in this decision.

159. Insight Health, Image Guided, Dr. O'Brien, and their employees and agents did not inform their patients, including Mr. Wingate, that they were receiving a knock-off drug produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems of NECC. They owed a duty to disclose this important fact to Mr. Wingate, explain to him why his medical condition warranted the use of a compounded drug, and obtain his informed consent to proceed with the dangerous procedure. None of this occurred.

160. On the contrary, Insight Health and its employees and agents provided their patients, including Mr. Wingate, with literature indicating that the injection that he would receive was Depo-Medrol, the trademarked name brand drug produced by Pfizer.

161. A representative copy of this literature is attached as **Exhibit C**.

162. Alternatively, Insight Health and its employees and agents provided patients, including Mr. Wingate, with such literature after the procedure but before payment for the services. Insight Health then obtained money from Mr. Wingate based upon its representation that he had been provided the name brand drug, Depo-Medrol.

163. On its website, Insight Health published similar representations about steroids used in image guided pain procedures (such as epidural steroid injections) provided at the Insight Imaging-Roanoke clinic. There, Insight Health falsely stated that patients would receive the name brand FDA-drugs, Celestone Soluspan or Depo-Medrol.

164. Insight Health purchased the clinic from Carilion in 2010. It then installed its proprietary software system called IRIS (Insight Radiology Information System). Under the IRIS system, the Insight Health employees enter coding information to reflect the procedures performed for a particular patient's records. This information is then used for billing purposes as well.

165. When Insight Health installed this system at the Insight Imaging-Roanoke clinic, its Executive Vice President, Pat Blank, specifically requested that the IRIS system should be altered so that injections of methylprednisolone acetate were reflected as "Depo-Medrol." This was then done.

166. Using its IRIS system, on September 6, 2012, Insight Health, through its employees, Karen DeLong or Sharon Boros, entered coding information into Mr. Wingate's records, establishing a record that Mr. Wingate had been injected with Depo-Medrol. It had done the same thing with hundreds of patients before him. This is what Insight Health trained these employees to do.

167. Based on this information maintained on the Insight Health computer system and entered into such system by these Insight Health employees, Insight Health or its agents also prepared invoices that incorrectly itemized the drug as “Depo-Medrol”, the trademarked name brand drug manufactured by Pfizer. Such an invoice was sent to Mr. Wingate.

168. The same invoices from Insight Imaging-Roanoke also incorrectly reference the National Drug Code (NDC), 0703-0051-01, (or an abbreviation of such code).

169. Insight Health’s corporate officer, Pat Blank, was also aware of the use of this incorrect NDC code when the IRIS system was set up for the Insight Imaging-Roanoke clinic. Correspondence was specifically directed to Pat Blank expressly indicating Insight Health’s goal of effectively charging for the 1ml vials of steroids used in epidural steroid injections. That correspondence contained screen shots of this incorrect National Drug Code, noting that the connection between the NDC code and the FDA.

170. A redacted true and correct copy of this invoice is attached as **Exhibit B**.

171. Further, the same Insight Health employees incorrectly coded methylprednisolone acetate on Mr. Wingate’s medical and billing records in the IRIS system, using billing code J1040. This is the HCPCS code tied to the name brand drug produced by FDA-regulated Pfizer, as well as other FDA-regulated generic drug producers, such as Teva Parenteral Medicines, Inc., a/k/a SICOR Pharmaceuticals.

172. A compounded drug should not be billed with the HCPCS codes meant for commercially prepared, preservative free drugs.

173. Rather, the “unlisted” code, J3490, should be provided along with the name of the drug and the dosage administered.

174. Insight Health, through its employees, who were specifically trained to do so, incorrectly coded methylprednisolone acetate on Mr. Wingate's medical and billing records using the National Drug Code, 0703-0051-01, a unique product code that contains an FDA-assigned labeler code unique to the manufacturer of the drug.

175. Rather than disclosing that the methylprednisolone acetate procured by Insight Health and injected into Mr. Wingate was a compounded drug from NECC, Insight Health through its IRIS system set-up and through the employees described above, used a completely unrelated and inapplicable NDC code assigned to the FDA-regulated drug manufacturer, Teva Parenteral Medicines, Inc., for single dose, 80 mg/mL, methylprednisolone acetate.

176. A copy of a representative label for the Teva Parenteral drug is attached for reference as **Exhibit D**.

177. However, Teva Parenteral Medicines, Inc., a leading generic drug manufacturer, had nothing to do with the epidural steroid injection that was provided to Mr. Wingate, and the drug was not even on the premises at the Insight Imaging-Roanoke clinic when Mr. Wingate received his injection.

178. Any reference in the records from Insight Health and its employees and agents to this Teva national drug code is simply wrong and completely misleading.

179. Insight Health and its employees and agents uniformly misrepresented that the knock-off drug obtained from NECC and injected into Mr. Wingate's spinal canal was, in fact, the name brand drug produced by Pfizer from an FDA-regulated laboratory and/or they misrepresented that it was the generic drug produced by the FDA-regulated laboratory, Teva Parenteral Medicines, Inc. Both representations were incorrect.

180. A redacted true and correct copy of a representative page from Mr. Wingate's medical/billing records from Insight Imaging-Roanoke is attached as **Exhibit F**.

181. Similarly, Dr. O'Brien's procedure notes for the ESI performed on Mr. Wingate on September 6, 2012 reflect that he was provided with an injection of Depo-Medrol. That is incorrect.

182. Reflecting injection of Depo-Medrol in Mr. Wingate's medical procedure notes (that were then contained in his records and forwarded to his primary care physician), was a breach of the standard of care that reflects the negligence with which Image Guided and Dr. O'Brien handled important medical decisions and documents for their patients, including Mr. Wingate.

183. The term, Depo-Medrol, referencing the trademarked, FDA-regulated drug, produced by Pfizer, simply cannot be used interchangeably to refer to the steroid from NECC. The NECC steroid only has one thing in common with Depo-Medrol, methylprednisolone acetate. It does not maintain relative suspension, has different steroid particle sizing, and is produced through a completely different process that is obviously inferior to the Pfizer drug. The NECC steroid is by no means the equivalent of, or reasonable approximation of, Depo-Medrol.

184. Dr. O'Brien asserts the form procedure notes were simply developed at a time when the clinic was actually using real "Depo-Medrol" and the form was never changed to reflect a different drug. Either Dr. O'Brien never really understood and knew that a change had been made to use the NECC knock-off steroid, or he assumed that the new drug was a therapeutically equivalent generic drug produced to the same high quality standards. Either way, it was below the standard of care and the duty of reasonable care to refer to the compounded

steroid from NECC as the drug, Depo-Medrol, in medical records and in materials provided to patients or made available to them.

185. Mr. Wingate never received Depo-Medrol or a drug produced to the same high quality standards from Insight Health, Image Guided, Dr. O'Brien, or their employees and agents.

186. A true and correct copy of Dr. O'Brien's report is attached as **Exhibit E**.

187. At all times and places pertinent to this action, the methylprednisolone acetate that Insight Health and its employees and agents voluntarily purchased from NECC and then sold and provided to their patients, including Mr. Wingate, was contaminated with fungus, mold, and/or other contaminants.

Mr. Wingate's Medical Timeline and Death

188. Mr. Wingate and his wife, Sharon, planned a cruise to celebrate their 25th wedding anniversary.

189. In order to more fully enjoy this special trip, Mr. Wingate spoke to his doctor about relieving the pain in his shoulder caused by a narrowing of his spine in the region of his neck.

190. Mr. Wingate was referred by his family practice physician for an epidural steroid injection.

191. The typical method for receiving an epidural steroid injection requires imaging capability, such as a fluoroscope, that allows the proper placement of the injection in exactly the correct place.

192. An anesthesiologist or an interventional radiologist typically performs an epidural steroid injection.

193. The first facility to which Mr. Wingate's doctor referred him could not provide the injection in time for the planned anniversary cruise, so Mr. Wingate obtained an appointment at Insight Imaging-Roanoke to receive the epidural steroid injection that would alleviate his pain.

194. On September 6, 2012 Mr. Wingate received the epidural steroid injection at Insight Imaging-Roanoke.

195. Mr. Wingate's epidural steroid injection was administered by Dr. O'Brien.

196. Unbeknownst to Mr. Wingate, the epidural steroid injection contained the adulterated drug that Insight Health and its employees and agents had purchased from NECC.

197. Within days of the epidural steroid injection, Mr. Wingate began suffering headaches.

198. By September 11, 2012 Mr. Wingate was confined to bed with a painful headache.

199. On September 12, 2012, at the insistence of his wife, Mr. Wingate was taken to the emergency room at a local hospital.

200. Upon taking his medical history and learning his symptoms, the emergency room medical staff tested for and confirmed he suffered from meningitis.

201. Mr. Wingate was admitted to the hospital and given antibiotics intravenously for the meningitis.

202. By September 14, 2012 Mr. Wingate's symptoms had worsened including, but not limited to, he was experiencing increasing sensitivity to light and noise.

203. While alert, Mr. Wingate would ask his medical providers if he would be well soon enough to go on the long anticipated cruise with his wife.

204. In the evening of September 14, 2012 Mr. Wingate suffered a series of strokes and became unresponsive, so he was transferred to the Intensive Care Unit.

205. On September 16, 2012 Mr. Wingate was confused but able to communicate to his wife.

206. However, Mr. Wingate then experienced more strokes and seizures in the evening, leaving him unresponsive and his brain activity ceased.

207. Mr. Wingate died on September 18, 2012 at the age of 47 when he was removed from life support.

208. Mr. Wingate's funeral was conducted on the same day he and his wife planned to leave on their anniversary cruise.

209. Mr. Wingate left behind a wife and two teenage children.

210. The medical examiner has confirmed the cause of Mr. Wingate's death as fungal meningitis caused by an injection of contaminated steroids.

211. Mr. Wingate's death was caused by his fungal meningitis.

212. Mr. Wingate's strokes were caused by his fungal meningitis.

213. Mr. Wingate's fungal meningitis was caused by the epidural steroid injection that he received on September 6, 2012 at Insight Imaging-Roanoke by Dr. O'Brien.

214. Mr. Wingate's fungal meningitis was the result of the actions by Insight Health and its employees and agents negligently purchasing a contaminated and adulterated drug from a compounding pharmacy (about which it had done no investigation or inquiry to justify such

purchases), negligently handling and preparing such drug, negligently failing to inform Mr. Wingate of the use of the drug, and then providing it to Mr. Wingate.

215. Mr. Wingate's fungal meningitis was the result of the negligent actions and inactions by Insight Health and its employees and agents.

216. Mr. Wingate's fungal meningitis was the result of the negligent actions and inactions by Image Guided, Dr. O'Brien, and their agents.

217. As the result of Mr. Wingate's untimely death, Mrs. Wingate is entitled to the recovery of funeral, burial, and medical expenses, as well as damages for her and their children's extreme mental anguish, sorrow, loss of companionship, loss of comfort, loss of guidance, loss of kindly offices, loss of services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

218. This lawsuit seeks fair compensation to the fullest extent permitted under the law of the Commonwealth of Virginia for Mr. Wingate's premature, painful, and agonizing death.

COUNT I – NEGLIGENCE *PER SE*

219. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

220. Virginia Code § 8.01-221 establishes that a person who is harmed by violation of a statute may recover for such harm.

221. Virginia law also establishes that:

. . . the violation of a statute or municipal ordinance adopted for public safety constitutes negligence because the violation is the failure to abide by a particular standard of care prescribed by a legislative body. A party relying on negligence *per se* does not need to establish common law negligence provided the proponent of the doctrine produces evidence supporting a determination that the opposing party violated a statute enacted for public safety, that the proponent belongs to the class of persons for whose benefit the statute was enacted and the harm suffered

was of the type against which the statute was designed to protect, and that the statutory violation was a proximate cause of the injury. Halterman v. Radisson Hotel Corp., 259 Va. 171, 176-77, 523 S.E. 2d 823, 825 (2000); Virginia Elec. & Power Co. v. Savoy Constr. Co., 224 Va. 36, 45, 294 S.E. 2d 811, 817 (1982).

Schlimmer v. Poverty Hunt Club, 268 Va. 74, 78-79, 597 S.E.2d 43, 46 (2004) (quotations omitted).

222. Virginia Code §§ 54.1-3400 et seq. (collectively known as “The Drug Control Act”) are statutes enacted for public safety, in that they protect the public from the release of substandard and otherwise unreasonably dangerous pharmaceutical drugs and drugs into the stream of Virginia commerce.

223. As a Virginia citizen and consumer of a drug regulated by the Virginia Drug Control Act, Mr. Wingate belonged to the class of persons for whose benefit those statutes were enacted.

224. A drug is deemed adulterated under Virginia law if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been rendered injurious to health. Va. Code § 54.1-3461(A)(2).

225. Additionally, a drug is considered adulterated if it purports to be a drug recognized in an official compendium, but fails to meet the quality or purity standards set forth in the compendium or the federal act. Va. Code § 54.1-3461(B).

226. By holding and offering for sale an adulterated drug to patients, including Mr. Wingate, Insight Health, Image Guided, and Dr. O’Brien violated Virginia Code § 54.1-3457(1), which is part of the Virginia Drug Control Act.

227. In doing so, Image Guided and Dr. O’Brien acted pursuant to a written and signed guaranty or undertaking, from Insight Health Corp., (a resident of Virginia and the party from

whom the adulterated drug was received), asserting that the drug was not adulterated or misbranded.

228. By receiving an adulterated drug in commerce and then delivering the drug for pay to its patients, including Mr. Wingate, Insight Health, Image Guided, Dr. O'Brien, and Dr. Mathis violated Virginia Code § 54.1-3457(3), which is part of the Virginia Drug Control Act.

229. In doing so, Image Guided, Dr. O'Brien and Dr. Mathis acted pursuant to a written and signed guaranty or undertaking, from Insight Health Corp., (a resident of Virginia and the party from whom the adulterated drug was received), asserting that the drug was not adulterated or misbranded.

230. Mr. Wingate died as the result of the actions of Insight Health, Image Guided, Dr. O'Brien, and Dr. Mathis (and, their respective agents and employees) in receiving, holding, selling, and providing to him an adulterated drug.

231. The adulterated drug injected into Mr. Wingate's spinal canal contained fungal pathogens that proximately caused him to develop fungal meningitis.

232. Death or injury of a patient resulting from consumption of or contact with adulterated drugs belongs to the category of harms against which the Virginia Drug Control Act was designed to protect.

233. Death or injury of a patient resulting from consumption of or contact with adulterated drugs distributed wholesale by an entity engaging in the wholesale distribution of prescription drugs in the Commonwealth of Virginia without a valid license belongs to the category of harms against which Virginia Drug Control Act was designed to protect.

234. Therefore, each of the violations of the above statutes (Virginia Code § 54.1-3457(1), and Virginia Code § 54.1-3457(3)) by Insight Health, Image Guided, Dr. O'Brien, and

Dr. Mathis (and their employees and agents) constitutes negligence per se, and Mrs. Wingate is entitled to the recovery of funeral, burial, and medical expenses, as well as damages for her and their children's extreme mental anguish, sorrow, loss of companionship, loss of comfort, loss of guidance, loss of kindly offices, loss of services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

COUNT II – VIRGINIA CONSUMER PROTECTION ACT

235. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

236. As defined in Virginia Code § 59.1-198, Mr. Wingate engaged in a consumer transaction with Insight Health, Image Guided, and Dr. O'Brien, (and their employees and agents).

237. Insight Health, Image Guided, and Dr. O'Brien, (and their employees and agents) were suppliers of the tainted methylprednisolone acetate injected into Mr. Wingate's spinal canal.

238. Insight Health, Image Guided, and Dr. O'Brien, (and their employees and agents) violated Virginia Code § 59.1-200, which prohibits suppliers from misrepresenting goods as those of another, misrepresenting the source, sponsorship, approval or certification of goods, and misrepresenting that goods are of a particular standard, quality, grade or model.

239. These willful violations by Insight Health, Image Guided, and Dr. O'Brien, (and their employees and agents) resulted in Mr. Wingate's death.

240. Mrs. Wingate is entitled to the recovery of funeral, burial, and medical expenses, as well as damages for her and their children's extreme mental anguish, sorrow, loss of

companionship, loss of comfort, loss of guidance, loss of kindly offices, loss of services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

241. All of these actual damages occurred as the result of the violations of Virginia Code § 59.1-200 by Insight Health, Image Guided, and Dr. O'Brien, (and their employees and agents).

242. Further, Mrs. Wingate is entitled to treble damages and an award of attorneys' fees, costs, and expenses incurred in this matter.

COUNT III – NEGLIGENCE

243. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

244. Insight Health, Image Guided, and Dr. O'Brien, (and their employees and agents) breached all of the duties owed to Mr. Wingate and identified in the preceding paragraphs.

245. Insight Health breached its professional duties to Mr. Wingate, including the duty of reasonable care. In addition to the specific breaches noted in the preceding paragraphs, and without limitation, these breaches included the following:

- a. Insight Health never did any investigation into NECC, in breach of its duty to do so. Had it done so, it would not have purchased from NECC. Insight Health's clinic manager, Paul Hellkamp, and both of the doctors at Image Guided, admit that even a Google Search showing that the pharmacy was surrounded by a garbage facility, would have raised red flags and caused concern.
- b. Insight Health remained unbelievably ignorant of the most basic facts relating to NECC and compounding pharmacies generally, despite its routine and repeated purchases of steroids from NECC.

- c. Insight Health treated NECC like a drug manufacturer, rather than a compounding pharmacy. Insight Health routinely purchased vast quantities of drugs from NECC, in violation of the rules for compounding pharmacies.
- d. Insight Health failed to understand and appreciate any distinction between a FDA-regulated drug manufacturer and a compounding pharmacy.
- e. Insight Health persisted in its refusal to conduct any investigation or inquiry into NECC despite overwhelming facts and circumstances that begged for such.
 - i. Insight Health had to improperly breach patient privacy expectations and regulations in order to even obtain steroids from NECC. Notwithstanding this, it did no investigation at all into NECC, the company that required it to do so.
 - ii. Insight Health completely disregarded the 2010 Bacterial Meningitis Case. Notwithstanding this extremely important event, it did no investigation at all into NECC.
 - iii. Insight Health completely disregarded the warnings of its corporate safety officer, Linda Massaro, during her 2012 inspection. Despite elevated corporate understanding of the completely unorthodox and improper prescription order sham in which Insight participated in order to obtain the NECC steroids, it still did no investigation at all into NECC.
 - iv. Insight Health completely disregarded the missing microbiology reports and certificates of analysis that were not received with the NECC steroids injected into Mr. Wingate. It did not quarantine the drugs, it did not

investigate NECC, and it continued to buy even more steroids from NECC.

- f. Insight Health failed to provide appropriate or reasonable goods and services and to appropriately bill for the goods and services that it provided.
- g. Insight Health failed to take proper care with the products and services offered to patients such as Mr. Wingate.
- h. Insight Health placed corporate profits over patient care in breach of its duties to Mr. Wingate.
- i. Insight Health failed to use reasonable skill, due diligence, and reasonable care in selecting, procuring, managing, investigating, maintaining, preparing, and inspecting drugs that were provided to Mr. Wingate.
- j. Insight Health failed to know and appreciate the source from which it obtained steroids provided to Mr. Wingate at the Insight Imaging-Roanoke clinic and the dangers associated with such procurement.
- k. Insight Health failed to properly inform Dr. O'Brien that it was purchasing methylprednisolone acetate from NECC, a compounding pharmacy rather than an FDA-regulated drug manufacturer. In failing to do so, Insight Health violated its duty and such violation prevented Dr. O'Brien from making knowledgeable and professionally reasonable decisions to reject such drug on behalf of Mr. Wingate and their other patients.
- l. Insight Health failed to properly inform Image Guided, Dr. Mathis and/or Dr. O'Brien that microbiology reports and sterility certificates were not provided by

NECC in connection with the steroids to be injected into Mr. Wingate and other patients.

- m. Having erroneously, recklessly, and negligently made the decision to procure a compounded parenteral steroid suspension for injection into Mr. Wingate from NECC, Insight Health failed to conduct a careful (or, for that matter, any) investigation and screening of the source compounding pharmacy, its methods and procedures, sterility practices, quality assurance practices, accreditation status, and legal compliance before purchasing parenteral medications such as the steroids injected into him.
- n. Having erroneously, recklessly, and negligently made the decision to procure a compounded parenteral steroid suspension for injection into Mr. Wingate from NECC, Insight Health failed to confirm and investigate the expiration or “beyond use” dating for such products to make sure that such dates were reasonable and in compliance with USP requirements and standards.
- o. Having erroneously, recklessly, and negligently made the decision to procure a compounded parenteral steroid suspension for injection into Mr. Wingate from NECC, Insight Health failed to act in accordance with and insist on purchasing drugs in accordance with accepted and applicable “beyond use” standards.
- p. Insight Health failed to properly handle, preserve, refrigerate, and use the NECC steroids within an appropriate time period.
- q. Having erroneously, recklessly, and negligently made the decision to procure a compounded parenteral steroid suspension for injection into Mr. Wingate from

NECC, Insight Health failed to visually inspect the compounding pharmacy where such drugs were to be produced.

- r. Having erroneously, recklessly, and negligently made the decision to procure a compounded parenteral steroid suspension for injection into Mr. Wingate from NECC, Insight Health failed to adequately inform Mr. Wingate of the source of medications which it procured and presented for injection into his body; and it failed to obtain his informed consent for the delivery of such drugs.
- s. Insight Health failed to inform Mr. Wingate that FDA-approved and regulated alternative steroid medications were available instead of the compounded drug.
- t. Insight Health failed to take reasonable steps with skill and diligence to ensure that the drugs that it procured and managed for delivery to Mr. Wingate at Insight Imaging-Roanoke were safe and effective.
- u. Insight Health failed to purchase and use only FDA-approved drugs for Mr. Wingate unless his special needs required compounding of drugs that were not commercially available. He had no such special needs, but if Insight Health believed that he did, it failed to inform him of this and the reasons why his needs required a compounded drug.
- v. Insight Health failed to properly and carefully handle, store, manage, and preserve the steroid that was provided to Mr. Wingate at the Insight Imaging-Roanoke clinic on September 6, 2012.
- w. Insight Health failed to properly, carefully and timely inspect the steroid that it provided to Mr. Wingate on September 6, 2012.

- x. Insight Health failed to inform itself and its employees of the dangers associated with compounded parenteral products such as the steroid that was provided to Mr. Wingate on September 6, 2012.
- y. Insight Health failed to operate the Insight Imaging-Roanoke clinic in such a way as to be aware of and avoid dangers posed by medication practices at such clinic. It failed to: (1) be informed and stay informed as to developments, dangers, and circumstances relevant to procurement of medications; (2) adequately inform Image Guided and its physicians of adverse health events that signaled possible problems with medications; (3) insure that proper paper work was received with medications; (5) act on the failure to receive proper paper work with medications; (5) use proper prescription processes for procuring compounded medications for Mr. Wingate and other patients; and (6) make sure that “informed consent” forms prepared by Insight Health accurately and completely disclosed the risks associated with the procedures and medications provided.
- z. Insight Health failed to act ethically.
- aa. Insight Health failed to act with integrity.
- bb. Insight Health failed to put patient care first.
- cc. Insight Health failed to do the right thing.
- dd. Insight Health put profits over ethics.
- ee. Insight Health put profits over integrity.
- ff. Insight Health put profits over patient care.

246. The structure and corporate organization imposed by Insight Health at the Insight Imaging – Roanoke Clinic was, in itself, a breach of the duty of reasonable care owed to Mr. Wingate and other patients. The system encouraged and created substandard medical care and

an atmosphere of shared negligence. The system was all about money and not about patient care. In establishing and then maintaining this system through September 6, 2012, when Mr. Wingate came to Insight Imaging-Roanoke, Insight Health breached its duties to Mr. Wingate and other patients.

247. Insight Health breached its duty to Mr. Wingate to keep accurate records of his medical treatment, to accurately bill him for services provided, and to provide him with accurate information as to the treatment and services provided to him at the Insight Imaging-Roanoke clinic.

248. Insight Health breached its duty to exercise reasonable care to ensure that the drugs that were purchased in order to sell and inject in patients at Insight Imaging-Roanoke, including Mr. Wingate, came from drug companies that complied with Virginia laws regarding pharmaceutical drugs ("The Virginia Drug Control Act" statutes).

249. Insight Health, Image Guided, and Dr. O'Brien, (and their employees and agents) breached their respective duties to exercise reasonable care to ensure that the drugs that were purchased in order to sell and administer to patients at Insight Imaging-Roanoke, including Mr. Wingate, were purchased from drug manufacturers that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated.

250. Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien breached their respective duties to provide adequate medical oversight regarding the purchase of drugs such as the one provided to Mr. Wingate.

251. Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien breached their respective duties to exercise reasonable care to avoid injecting Mr. Wingate with adulterated drugs.

252. Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien breached their respective duties to know and understand the drug (including its source and supply) that they were injecting into patients, including Mr. Wingate.

253. Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien breached their respective duties to exercise reasonable and prudent care to ensure that the drug that they provided to Mr. Wingate was produced in sanitary, sterile conditions.

254. Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien breached their respective duties to provide Mr. Wingate reasonable care and treatment when he came to them for treatment.

255. Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien breached their respective duties to obtain informed consent from Mr. Wingate for the procedure performed on him. They failed to adequately and accurately describe to him the source of the compounded drugs to be used, the reasons a compounded drug was required for his specific medical needs, the nature of the procedure, the risks of such procedure, and the fact that the epidural steroid injection was an "off-label" application of the drug at issue, not approved by the FDA for such application.

256. Image Guided and Dr. O'Brien breached their duties to Mr. Wingate by delegating important patient care functions of choosing safe drugs for patients to improperly trained, improperly educated, and improperly supervised personnel or entities. In so doing, they deviated from the standard of care and breached their duties to Mr. Wingate.

257. Image Guided and Dr. O'Brien are responsible for the actions and inactions of Insight Health with regard to the allegations set forth in Paragraph 245. By failing to supervise, understand and regulate the actions and inactions of Insight Health regarding functions that were delegated or assigned to Insight Health as part of the corporate structure of the operations of Insight Imaging-Roanoke, Image Guided and Dr. O'Brien breached their duties as healthcare providers to Mr. Wingate.

258. Image Guided and Dr. O'Brien further breached their duties to Mr. Wingate by, without limitation, the following:

- a. They never did any investigation into NECC, in breach of its duty to do so. Had they done so, they would not have injected drugs from NECC into Mr. Wingate or other patients.
- b. They remained unbelievably ignorant of the most basic facts relating to NECC and compounding pharmacies generally, despite their routine and repeated injection of steroids from NECC.
- c. They allowed Insight Health to purchase drugs from NECC like it was a drug manufacturer, rather than a compounding pharmacy, in violation of the rules for compounding pharmacies.
- d. They failed to understand and appreciate any distinction between an FDA-regulated drug manufacturer and a compounding pharmacy.
- e. They persisted in refusal to conduct any investigation or inquiry into NECC despite overwhelming facts and circumstances that begged for such.
 - i. Their patients' privacy expectations and regulations governing such had to be breached in order to even obtain steroids from NECC. Dr. Mathis'

DEA number and name were used as part of this improper process. Notwithstanding this, they did no investigation at all into NECC, the company that required them to do so.

- ii. They completely disregarded the 2010 Bacterial Meningitis Case. Notwithstanding this extremely important event, they did no investigation at all into NECC and they continued to inject the dangerous drugs from NECC.

- f. They failed to provide appropriate or reasonable goods and services and to appropriately document and ensure that their agents properly billed for the goods and services that they provided.
- g. They failed to take proper care with the drugs and services offered and provided to patients such as Mr. Wingate.
- h. They failed to take reasonable steps to assure that proper and reasonable skill, due diligence, and reasonable care was exercised in selecting, procuring, managing, investigating, maintaining, preparing, and inspecting drugs that were provided to Mr. Wingate.
- i. They failed to know and appreciate the source from which the Insight Imaging-Roanoke clinic obtained steroids provided to Mr. Wingate at the Insight Imaging-Roanoke clinic and the dangers associated with such procurement. Through this ignorance, they then failed to do all or any of the things and duties implicated by the epidural use of compounded steroids.
- j. They failed to properly inform themselves of that the drugs injected into Mr. Wingate were methylprednisolone acetate from NECC, a compounding pharmacy rather than

an FDA-regulated drug manufacturer. In failing to do so, they violated their duty to make knowledgeable and professionally reasonable decisions on behalf of Mr. Wingate and their other patients.

- k. To the extent that they knew of, and, therefore, chose to inject NECC methylprednisolone acetate into Mr. Wingate and other patients, they failed to conduct a careful (or, for that matter, any) investigation and screening of the source compounding pharmacy, its methods and procedures, sterility practices, quality assurance practices, accreditation status, and legal compliance before injecting such compounded steroids into him.
- l. To the extent that they knew of and, therefore, chose to inject NECC methylprednisolone acetate into Mr. Wingate and other patients, they failed to confirm and investigate the expiration or “beyond use” dating for such products to make sure that such dates were reasonable and in compliance with USP requirements and standards.
- m. To the extent that they knew of and, therefore, chose to inject NECC methylprednisolone acetate into Mr. Wingate and other patients, they failed to act in accordance with and insist on injecting purchased and prepared in accordance with accepted and applicable “beyond use” standards.
- n. They failed to take any reasonable steps to assure that the drugs injected into Mr. Wingate were properly handled, preserved, refrigerated, and used within an appropriate time period.
- o. To the extent that they knew of and, therefore, chose to inject NECC methylprednisolone acetate into Mr. Wingate and other patients, they failed to

visually inspect or have others visually inspect the compounding pharmacy where such drugs were to be produced.

- p. To the extent that they knew of and, therefore, chose to inject NECC methylprednisolone acetate into Mr. Wingate and other patients, they failed to adequately inform Mr. Wingate of the source of medications that were to be injected into his body; and they failed to obtain his informed consent for the injection of such drugs.
- q. They failed to inform Mr. Wingate that FDA-approved and regulated alternative steroid medications were available instead of the compounded drug.
- r. They failed to take reasonable steps with skill and diligence to ensure that the drugs that injected into Mr. Wingate were safe and effective.
- s. They failed to use only FDA-approved drugs for Mr. Wingate unless his special needs required compounding of drugs that were not commercially available. He had no such special needs, but if they believed that he did, they failed to inform him of this and the reasons why his needs required a compounded drug.
- t. They failed to assure or take reasonable steps to make certain that the steroid provided to Mr. Wingate was properly and carefully handled, stored, managed, and preserved.
- u. They failed to properly, carefully and timely inspect the steroid that they injected into Mr. Wingate on September 6, 2012, specifically failing to inspect the vial and draw the medications.

- v. They failed to inform themselves and their agents of the dangers associated with compounded parenteral products such as the steroid that was provided to Mr. Wingate on September 6, 2012.
- w. They failed to operate their medical practice in such a way as to be aware of and avoid dangers posed by medication practices at Insight Imaging-Roanoke. They failed to: (1) be informed and stay informed as to developments, dangers, and circumstances relevant to procurement of medications; (2) adequately inform themselves and address adverse health events that signaled possible problems with medications; (3) insure that proper paper work was received with medications; (5) act on the failure to receive proper paper work with medications; (5) use proper prescription processes for procuring compounded medications for Mr. Wingate and other patients; and (6) make sure that “informed consent” forms prepared by Insight Health accurately and completely disclosed the risks associated with the procedures and medications provided.

259. The negligence of Insight Health, Image Guided, Dr. Mathis, Dr. O'Brien and their employees and agents proximately caused Mr. Wingate's illness and death.

260. Mrs. Wingate is entitled to the recovery of funeral, burial, and medical expenses, as well as damages for her and her children's extreme mental anguish, sorrow, loss of companionship, loss of comfort, loss of guidance, loss of kindly offices, loss of services, and all other items of damage provided by the Virginia Death by Wrongful Act statutes.

COUNT IV – GROSS NEGLIGENCE

261. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

262. The foregoing acts and omissions by Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien and their employees and agents went beyond mere thoughtlessness, inadvertence or error of judgment.

263. Rather, the actions and inactions of Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien and their employees and agents did not meet even the most minimal diligence to ensure that they were not injecting adulterated and tainted drugs directly into the bodies of their patients, including Mr. Wingate.

264. The acts and omissions of Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien and their employees and agents constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Mr. Wingate.

265. The acts and omissions of Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien and their employees and agents were a heedless and palpable violation of their legal duties respecting the life and rights of Mr. Wingate. *Frazier v. City of Norfolk*, 234 Va. 388, 393, 362 S.E.2d 688, 691 (1987).

266. Mr. Wingate's death occurred as a proximate result of the grossly negligent acts and omissions of Insight Health, Image Guided, Dr. Mathis, and Dr. O'Brien and their employees and agents.

COUNT V – FRAUD

267. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

268. This count alleges only constructive fraud against Image Guided and Dr. O'Brien.

269. This count alleges constructive and actual fraud against Insight Health.

270. Insight Health, Image Guided, Dr. O'Brien and their employees and agents did not inform their patients, including Mr. Wingate, that they were providing drugs produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems described in the preceding paragraphs.

271. Insight Health, Image Guided, Dr. Mathis, Dr. O'Brien and their employees and agents had a duty to inform their patients of these facts which were possessed solely by them and which they knew were unknown to Mr. Wingate and other patients.

272. Insight Health, Image Guided Dr. O'Brien and their employees and agents provided Mr. Wingate with a knock-off drug obtained from an unaccredited compounding pharmacy, unregistered to distribute wholesale in Virginia, and not preferred by insurance companies – including Mr. Wingate's insurance company, without disclosing information about its source.

273. In so doing, Insight Health, Image Guided Dr. O'Brien and their employees and agents concealed facts material to Mr. Wingate's treatment, knowing Mr. Wingate acted on the belief that no such facts existed, and that Mr. Wingate relied upon them to obtain and inject safe drugs.

274. Such actions by Insight Health and its employees and agents constituted actual and/or constructive fraud.

275. Such actions by Image Guided and Dr. O'Brien constituted constructive fraud.

276. Insight Health and its employees and agents had a duty to adequately inform the doctors practicing at the Insight Imaging-Roanoke, including Drs. Mathis and O'Brien, about the purchasing decisions by Insight Health to obtain drugs from NECC and about NECC. To the extent it did not do so, it violated its duty and such violation prevented Image Guided and Dr. O'Brien from making knowledgeable and professionally decisions to reject such drugs on behalf of Mr. Wingate and their other patients.

277. Insight Health, through its employees, provided patients, such as Mr. Wingate, with written false documentation asserting that the drug to be injected or, that had been injected, was, in fact, the name brand drug produced by the FDA-regulated manufacturer, Pfizer. (See **Exhibit C.**)

278. Specifically, the Insight Health receptionist provided Mr. Wingate with these written materials stating that he was to be injected with 80mg of the name brand drug, Depo-Medrol. This was done prior to his injection.

279. Mrs. Wingate recalls that such literature was provided by Insight Health's receptionist before the procedure was done.

280. The name of the receptionist is unknown, but may be determined by Insight Health. Mrs. Wingate described her as a Caucasian woman with short black hair, glasses, heavy-set and in her 40's.

281. Alternatively, Insight Health's employees assert that such literature was provided to Mr. Wingate after his procedure, but before he provided his co-payment to Insight Health.

282. If this account is correct, Insight Health employee, Karen DeLong, provided Mr. Wingate with written materials stating that he was injected with 80mg of the name brand drug,

Depo-Medrol. This was done prior to Mr. Wingate paying his co-payment for the injection. Immediately after receiving these written materials from Insight Health's employee, Karen DeLong, Mr. Wingate wrote a check to Insight Health in reliance upon the information provided by Insight Health.

283. Insight Health obtained money from Mr. Wingate based upon these fraudulent statements.

284. Also, Insight Health, through its employee, Karen DeLong, entered improper and false information into Mr. Wingate's medical records on the IRIS system, resulting in written false drug code documentation asserting that the drug injected into the patient was, in fact, the generic version of the drug produced by the FDA-regulated manufacturer, Teva Parenteral Medicines, Inc., National Drug Code, 0703-0051-01 (single dose, 80 mg/mL, preservative free, methylprednisolone acetate). Ms. DeLong was specifically trained to do so by Insight Health corporate employees.

285. Mr. Wingate relied upon all information provided by Insight Health regarding the treatment and services provided to him at the Insight Imaging – Roanoke clinic. He further relied upon the superior knowledge of Insight Health concerning the drug, source of the drug, and cost of the drug in accepting its representations.

286. By representing that the drug injected was obtained from an FDA-regulated manufacturer, Insight Health misrepresented a material fact regarding Mr. Wingate's treatment.

287. Rather than properly informing its patients, including Mr. Wingate, of these crucial facts, Insight Health and its employees and agents falsely represented the drug at issue as "Depo-Medrol," the trademarked name brand used by Pfizer; and falsely coded it as the generic version of the drug produced by the FDA-regulated manufacturer, Teva Parenteral Medicines,

Inc., National Drug Code, 0703-0051-01 (single dose, 80 mg/mL, preservative free, methylprednisolone acetate).

288. This pattern of deception by Insight Health and its employees and agents was also repeated for billing purposes to Mr. Wingate's insurance company, where Insight Health, through its employee, Karen DeLong (who entered to information at issue into the IRIS system) falsely used the National Drug Code, 0703-0051-01, a unique product code assigned to the completely unrelated FDA-regulated drug manufacturer, Teva Parenteral Medicines, Inc.

289. Insight Health also falsely used an HCPCS "J" code inappropriate and misleading for compounded drugs. This information was entered by Insight Health employee, Karen DeLong.

290. Such actions by Insight Health and its employees and agents show affirmative misrepresentations of the identity of the drug provided to Mr. Wingate and a knowing, deliberate decision not to disclose the source of the "drug" provided to Mr. Wingate.

291. As a third party payor and agent authorized to receive medical invoices for processing on behalf of Mr. Wingate, misrepresentations to Mr. Wingate's health insurer constitute misrepresentations to him.

292. Mr. Wingate's health insurer, like many such third-party payors, maintains policies discouraging the use of compounded drugs.

293. For example, Anthem Blue Cross states as follows:

Compounded medications are customized medication(s) ... that are not commercially available ... However, they are not approved by the U.S. Food and Drug Administration (FDA) nor are they approved by our Pharmacy and Therapeutics process. **Since there is limited oversight in the preparation of these compounded medications, there is a possibility that patients may be put at risk when prescribed a compounded medication that is not subject to quality testing that validates purity, stability or dosage...** Thus, due to the lack of data to adequately review these medications, compounded medications are

considered **non-preferred**... They may also require prior authorization of benefits for coverage through a participating network pharmacy...

294. On information and belief, Insight Health and its employees and agents knew that using drugs from compounding pharmacies would present billing issues and problems with reimbursement.

295. On information and belief, Insight Health and its employees and agents knew that properly coding the drugs injected into Mr. Wingate and other patients would cause concerns and “red flags” with insurance companies, such as the one serving Mr. Wingate.

296. Accordingly, Insight Health and its employees and agents specifically chose to falsely describe the drugs provided as part of a scheme and common practice or design, intended to prevent insurance companies from realizing the nature and source of the drugs being injected into patients, such as Mr. Wingate. Insight Health did the exact same thing with hundreds of other patients such as Mr. Wingate.

297. Insurance companies, such as the one serving Mr. Wingate, act as a protective information source and gatekeeper for their customers.

298. These specific actions relating to Mr. Wingate and the prolonged pattern of deception prevented Mr. Wingate’s insurer from properly performing its protective role. As a result, Insight Health was able to continue its practice of purchasing methylprednisolone acetate from NECC and passing it off as a manufactured and safe drug.

299. Under these circumstances, misrepresentations to Mr. Wingate’s insurer – particularly as part of a pattern of conduct – constituted misrepresentations to Mr. Wingate that were material and relied upon to his detriment.

300. Insight Health and its employees and agents misrepresented that the knock-off drug obtained from NECC and injected into Mr. Wingate’s spinal canal was, in fact, the name

brand drug produced by Pfizer from an FDA-regulated laboratory; they misrepresented the code for such drug as the generic drug produced by the FDA-regulated laboratory, Teva Parenteral Medicines, Inc.

301. These representations (and the pattern of which they were a part) were false and deceptive, were relied upon to the detriment of Mr. Wingate (and/or his agent insurer) and other patients, and caused harm to and the death of Mr. Wingate.

302. Insight Health and its employees and agents knew, or should have known, these representations to be false.

303. These representations and the pattern of similar behavior by Insight Health and its employees and agents constitute actual or constructive fraud.

304. With regard to this Count, and in addition to the other relief requested as damages arising under this Count, the Plaintiff specifically seeks additional damages in the amount of the funds paid to Insight Health by Mr. Wingate and his insurer.

CERTIFICATION PURSUANT TO VIRGINIA CODE § 8.01-50.1

305. Mrs. Wingate certifies that she complied with Virginia Code § 8.01-50.1 before requesting service of process upon the defendants.

REQUEST FOR TRIAL BY JURY

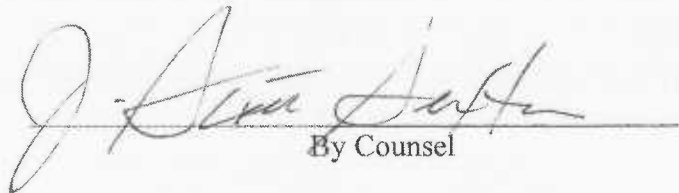
306. Mrs. Wingate requests trial by jury on all issues.

PRAYER FOR RELIEF

WHEREFORE, Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, by counsel, moves this Court for judgment against the defendants, jointly and

severally, in the amount of TWENTY FIVE MILLION DOLLARS (\$25,000,000) plus her taxable costs with pre-verdict interest from September 6, 2012 and post-verdict interest on all of these amounts, as well as \$350,000 in punitive damages, trebled damages, attorney's fees, and costs.

SHARON G. WINGATE, EXECUTOR OF THE
ESTATE OF DOUGLAS GRAY WINGATE,
DECEASED,



By Counsel

J. Scott Sexton, Esq. (VSB No. 29284)
Anthony M. Russell, Esq. (VSB No. 44505)
Charles H. Smith, III, Esq. (VSB No. 32891)
H. David Gibson, Esq. (VSB No. 40641)
Benjamin D. Byrd, Esq. (VSB No. 76560)
Daniel R. Sullivan, Esq. (VSB No. 81550)
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gibson@gentrylocke.com
byrd@gentrylocke.com
sullivan@gentrylocke.com

*Counsel for Sharon G. Wingate, Executor of the
Estate of Douglas Gray Wingate, deceased*

CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of December, the foregoing was served via electronic and regular mail upon:

Christopher E. Hassell, Esq.
Brian J. Gerling, Esq.
Clinton R. Shaw, Esq.
Heather S. Deane, Esq.
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Counsel for Defendant Insight Health Corp.

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michael.gardner@leclairryan.com

Counsel for the defendants Image Guided Pain Management,
John Mathis, M.D., and Robert O'Brien, M.D.

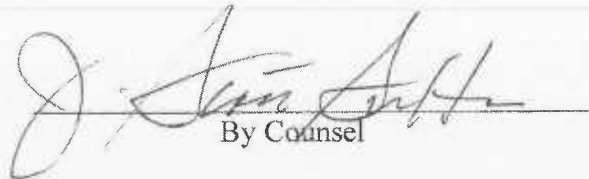

By Counsel



EXHIBIT A

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John M. Mathis, M.D., M.Sc.

INSIGHT
IMAGING

INSIGHT IMAGING - ROW ONE
2921 FRANKLIN FIELDS AVE
ROANOKE VA 24012

Tel: 540.581.0882
Fax: 540.581.0881

www.insighthealth.com

Date: _____

Injection dosage: Depo-Medrol 80mg / 40mg

Steroids typically take 12 to 24 hours before they start to work.
Maximum effect can take up to 7 - 10 days.

Call Insight Imaging (540-581-0882) in a week if symptoms have not subsided to schedule another injection. If you already have an appointment scheduled with Insight, keep that appointment unless otherwise directed by your physician.

If your pain has completely resolved, and you no longer need your follow up appointment, please call Insight Imaging to cancel your future injection.

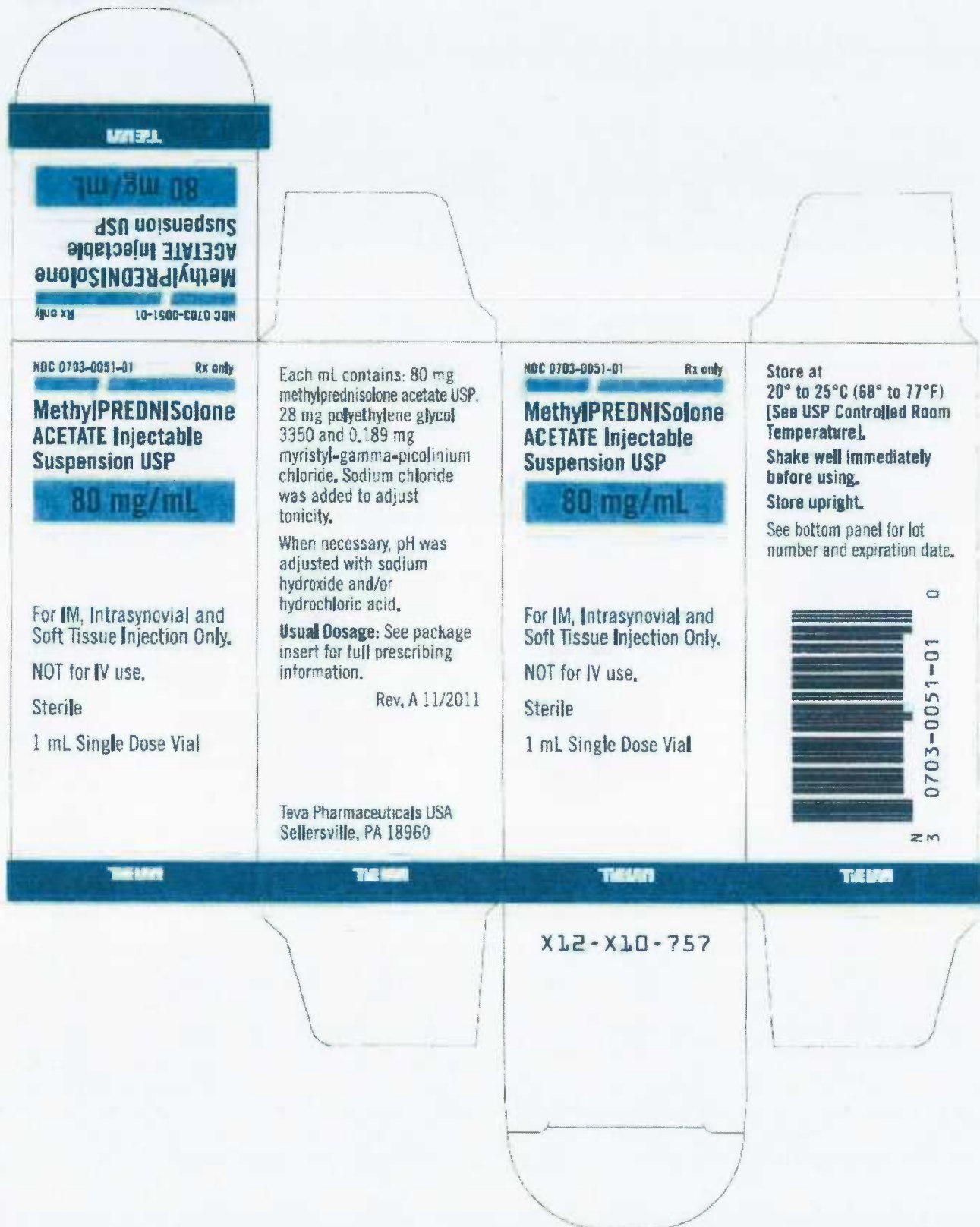
Continue to take pain meds if needed.
Heat or ice may be used as well.

Symptoms can worsen before seeing improvement.

****Call your Doctor that monitors your Diabetes or Blood Pressure if you feel you are higher than the guidelines set by your physician.

EXHIBIT C

PRINCIPAL DISPLAY PANEL





Insight Imaging – Roanoke
2923 Franklin Road
Roanoke, VA 22206
PH# 540.581.0882
FAX# 540.581.0881

PATIENT NAME: WINGATE, DOUGLAS
PATIENT DOB:
DATE OF EXAM: 09/06/2012
REQUESTED BY: CHRISTY ARTHUR, MD

EXAM: INJ 1 NOT LYTIC-W/WO CM-DX/TX-EPIDUR; CERV/THOR

CLINICAL HISTORY: Cervical radiculopathy.

INJECTION SITE: The study was performed near the midline at C5-C6.

Following sterile preparation and drape and with the use of lidocaine as local anesthetic, a 25-gauge spinal needle was advanced under fluoroscopic guidance to the posterior epidural space. The study was performed near the midline at C5-C6. Small puffs of contrast were administered to confirm needle tip location. Once needle tip location in the posterior epidural space was confirmed, a mixture of Depo-Medrol and saline was administered. A total 80 mg of Depo-Medrol was given. The patient tolerated the procedure well and left the department in stable condition.

IMPRESSION:
SUCCESSFUL CERVICAL EPIDURAL STEROID INJECTION UNDER FLUOROSCOPIC GUIDANCE

Thank you for this referral.

Robert F. O'Brien, M.D.

RFO/mm

D: 09/06/2012 06:09:36PDT

T: 09/06/2012 06:34:18PDT

Doc ID: 12087066/Insight Job ID: 2315558/NTS Job ID: 2315558/10243381
10243381

Document authenticated by Robert F. O'Brien, M.D., on 09/06/2012 08:01:53PDT

EXHIBIT F

<input checked="" type="checkbox"/> Procedure Completion		<input type="checkbox"/> Exam 1 of 1													
Patient Name: WINGATE DOUGLAS DOB: 9/5/2012 Sex: M Age: 47 SSN: [REDACTED] Is Patient Pregnant: No Date of LMP: MM/DD/YYYY		Visit: Service Date: 9/5/2012 Appt Type: S													
Accession: 10243381 CPT Code: 62310 CPT Description: EPIDURAL CERVTX		Modality: SPC Start Time: 8:30 AM End Time: 9:00 AM													
Performed Procedure: 10243381 Prim Diag: FD CPT Cd/Desc: 62310 EPIDURAL(CERV) CERVTX Additional Charges:															
Contrast Seq w/ Contrast Seq w/ Radiologist: DOBRIEN No Dose S/S: [REDACTED] DLR IN: 39 cm Misc: [REDACTED]															
Contrast/Isotope/Sedation/Supplies:															
<table border="1"> <tr> <td>Accession</td> <td>NDC</td> <td>Accession</td> </tr> <tr> <td>2109966</td> <td>00270141125</td> <td>10243381</td> </tr> <tr> <td>11040</td> <td>00703005101</td> <td>10243381</td> </tr> <tr> <td>1144216</td> <td>00409488820</td> <td>10243381</td> </tr> </table>				Accession	NDC	Accession	2109966	00270141125	10243381	11040	00703005101	10243381	1144216	00409488820	10243381
Accession	NDC	Accession													
2109966	00270141125	10243381													
11040	00703005101	10243381													
1144216	00409488820	10243381													
Sedation/Meds:															
Brand: DEPO-MEDROL METHYL-PREDNISOLONE Strength: 80 MG/ML Route: EPIDURAL Delivery: 1 ML NDC #: 00703005101 Amt Admin: 1 ML Sedation Note: [REDACTED] Lot #: 06292012 Admin By: RFO (Initials) Exp On: 12/26/2012 C: [REDACTED]															

EXHIBIT G



Insight Health Corp.
New York Billing Office
8750 Transit Road, Suite 215
E. Amherst, NY 14267
Tel: (866) 674.9985
Fax: (716) 564.1243

Dear Valued Patient,

Insight Health Corp. is committed to providing our patients with superior diagnostic imaging services and to bill appropriately for the services we provide. During a recent routine audit it was determined that you overpaid for the services we provided. We are therefore enclosing a check for the amount of that overpayment and apologize for the delay.

If you feel this refund may have been made in error or have any questions about your refund, please contact our billing office at (866) 674-9985.

Thank you.

Billing Department
Insight Health Corp.

00157040 105112788 329904194



AUTHORIZED SIGNATURE

[Handwritten Signature]

TO THE ORDER OF
DOUGLAS WINGATE
61 FRANTZ ST
SALEM, VA 24153

AMOUNT \$81.56

PAY Eighty-one and 56 / 100 Dollars Only *****

DATE 10/17/2012 CHECK NUMBER 00157040

INSIGHT IMAGING
Insight Health Corp
26250 Enterprise Court, Suite 100
Lake Forest, CA 92630-8405

BANK OF AMERICA
DeKalb County
Atlanta, GA

64-1278/611

DOCUMENT IS PRINTED ON CHEMICALLY REACTIVE PAPER • THE BACK OF THIS DOCUMENT INCLUDES A TAMPER EVIDENT CHEMICAL WASH WARNING BOX

DOUGLAS WINGATE		DATE	10/17/2012	CHECK NUMBER	00157040
INVOICE NUMBER	ROANOK-23614	INVOICE DATE	10/15/2012	VOUCHER NUMBER	Vch: V001015791
					DOUGLAS WINGATE 9/6/12